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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,633

04/09/2004

Zia Yassinzadeh

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EXAMINER

DANG, PHONG SON H

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,633	Applicant(s) YASSINZADEH, ZIA	
	Examiner SON DANG	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-11,14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-11,14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/13/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. Claims 1, 3-5, 7-11, 14 and 17-21 are pending in the application. Claims 2, 6, 12-13, 15-16 and 22-67 have been cancelled.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-11 recites the limitation "the balloon" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,419,765 to Weldon et al. (Weldon).

In Regards to claims 1, 5, 8-11:

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Weldon teaches:

A method for hemostasis of a puncture site in a wall of a blood vessel at an end of a tissue tract having a sheath (10, Fig. 22A) therein, the method comprising: providing a locating member (120, Fig. 22B) having a proximal end, a distal end, and an expansible member (124, Fig. 22B) disposed on the distal end thereof, inserting the locating member (120, Fig. 22B) through the sheath (10, Fig. 22B) in the tissue tract so that the expansible member (124, Fig. 22C) on the locating member (120, Fig. 22C) enters a lumen of the blood vessel; expanding the expansible member (124, Fig. 22C) on the inserted locating member (120, Fig. 22C) and drawing the inserted locating member (120, Fig. 22C) proximally so that the expanded expansible member (124, Fig. 22C) covers the puncture site in the vessel wall; removing the sheath (Fig. 22C) from the tissue tract while the inserted locating member (120, Fig. 22C) remains in place; providing a tubular compression member (56, Fig. 24A) having a proximal end, a distal end, a central passage (126, Fig. 22D) between said proximal end and said distal end, and an expansible tissue compression element (64, Fig. 24A) disposed over the distal portion thereof, and advancing the tubular compression member (56, Fig. 24A) over the inserted locating member (120, Fig. 24A) after the sheath (10, Fig. 22A) has been removed from the tissue tract so that the locating member (120, Fig. 22D) is received in the central passage (126, Fig. 22D) of the tubular compression member (56, Fig. 24A) and the expansible tissue compression element (64, Fig. 24C) is located within the tissue tract at a

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predetermined distance proximal from the wall of the blood vessel to define a tissue compression region; and expanding the expansible tissue compression element (64, Fig. 24C) within the tissue tract above the blood vessel wall to apply pressure against subcutaneous tissue and to compress said tissue over the puncture site in the blood vessel wall (The membrane 64 is compressing over the predetermined space which the hemostasis material is occupied) to promote hemostasis, wherein the expansible tissue compression element (64, Fig. 24C) on the compression member (56, Fig. 24C) is left in place until hemostasis has been achieved. The expansible element being a balloon (124, Fig. 22C). Inflating a distal face of the balloon at an angle to the compression member, expanding comprises inflating the balloon (32, Fig. 22F) to a deployed configuration comprising a conical shape, unfolding concentric folds of the balloon (membrane 64 is folded in Fig. 24A before being unfold/inflate in Fig. 24C), inflating the balloon (64, Fig. 24C) to a deployed configuration having a concave distal end (Fig. 22F).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 3-4, 7, 14 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon. Weldon does not disclose the predetermined distance is in a range from about 0.05 inch to about 0.5 inch or 0.2 inch to about 0.3 inch, the expansible member deployed diameter, contracting and withdrawing the locating member while the compression member remains in place, imaging the element during positioning, delivering energy to the puncture site, delivering a clot promoting agent or an anti-infection agent to the puncture site, or instructions on how to use the device. It would also be obvious to modify the predetermined depth of the expandable balloon in the tissue tract as well as to modify the expansible member's diameter in order to fit the correct size puncture and provide enough pressure to cause hemostasis to occur. It would have been obvious to withdraw the locating member first and leave the compression member to further help the hemostasis process while withdrawing the locating member instead of withdraw them all at the same time. It is well-known in the art to image an insertion area in order to determine the exact location of where the device is moving through the tissue. It is also well-known in the art to use some form of energy for either imaging purposes or to seal the puncture site. It is further well-known in the art to use both clot promoting agents and anti-infection agents to help seal a wound/puncture in a vessel. It would be obvious to provide instructions on how to use the device of Weldon in order to allow a user to properly insert it and use it within and around a vessel.

Response to Arguments

9. Applicant's arguments with respect to claims 1, 3-5, 7-11, 14 and 17-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. D./
Examiner, Art Unit 3773

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